K120790

JUN - 8 2012

Medacta International

510(k) Summary

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Date Prepared: 03/08/2012

DEVICE INFORMATION

Trade/Proprietary Name: GMK - Line Extension
Common Name: Total Knee Prosthesis
Classification Name: Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer

21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:

K090988 GMK Total Knee System (Medacta International)
K081023 Evolis Total Knee System (Medacta International)
K102437 GMK Total Knee System - Revision (Medacta International)
K103170 GMK Revision SC Liners (Medacta International)

Product Description

The GMK - Line Extension is comprised of the GMK Femur Size 7 and the GMK Revision extension stems.

Indications for Use

The GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices

The GMK - Line Extension has the same intended use, material, and performance characteristics as the predicate devices.

Performance Testing

A review of the mechanical data indicates that the GMK – Line Extension is equivalent to devices currently cleared for use and is capable of withstanding expected in vivo loading without failure.

The modification to the GMK system to include the addition of the GMK Femur Size 7 and the GMK Revision extension stems was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was conducted on the worst case component size and option/design based on engineering analysis.

The GMK Femur Size 7 was compared to the GMK Femur Size 1 (worst case) in terms of volume for cement insertion, contact surface area, risk of dislocation, and mechanical strength. The GMK Femur Size 7 has a larger volume for cement insertion which reduces the risk of loosening of cement fixation. The GMK Femur Size 7 also has a larger contact surface area which reduces the contact stress between the tibial insert and the femoral component. The GMK Femur Size 7 has an adequate level of constraint to prevent dislocation because of the larger thickness and contact area as compared to the worst case. The GMK Femur Size 7 also has greater mechanical strength than the worst case.

The GMK Revision extension stems were tested and an analysis was performed to identify the worst cases compared to the modified devices. Endurance property testing was conducted to applied standards per FDA guidance "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis; Guidance for Industry and FDA", issued on Jan. 16, 2003. The GMK Revision extension stems met all of the requirements according to the FDA Guidance document.

Conclusion:
Based on the above information, the GMK - Line Extension can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mr. Adam Gross
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Re: K120790
Trade/Device Name: GMK Line Extension
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint, patellofemorotibial, polymer/metal/polymer, semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: May 9, 2012
Received: May 10, 2012

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 120790

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120790

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)